

Application No. 10,810,089
Amendment dated July 13, 2005
Reply to Office Action dated April 14, 2005

Amendments to the Drawings

The attached Replacement Sheet of drawing includes changes to Figure 2. This Replacement Sheet replaces the original sheet including Figures 2-4. In Figure 2, reference numbers 340, 341 and 345 have been changed to 40, 41, and 45, respectively, as set forth in the description.

Attachment: One Replacement Sheet

REMARKS

Applicants have carefully reviewed the Office Action dated April 14, 2005. In the Office Action, claims 1-5, 7, 8, 12, 13, 15, 17, 18 and 20-23 were rejected and claims 6, 9-11, 14, 16, 19 and 24-40 were withdrawn. The drawings were objected to.

Drawings

The drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) as they do not include the following reference sign(s) mentioned in the description: 40, 41, and 45. Figure 2 has been amended to refer to these reference signs. Specifically, references signs 340, 341, and 345 have been changed to 40, 41 and 45, respectively. Applicants therefore submit that the objection is obviated.

Claim Rejections—35 U.S.C. § 102

Claims 1, 2, 4, 5, 7, 8, 12, 13, 15, 22 and 23 have been rejected under 35 U.S.C. §102(b) as being anticipated by Hegde et al. (U.S. Patent No. 6,231,543). Applicants respectfully traverse the rejection.

Hegde et al. disclose a dilation catheter having a catheter shaft with an inner guidewire lumen and an inflatable balloon. However, Hedge et al. do not disclose a radiopaque coating as claimed in claim 1, namely “a radiopaque coating disposed on a surface of a portion of the elongated shaft, the radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment of the shaft in a fluid state and cured”

Hegde et al. disclose an embodiment that includes a sleeve 50 that is secured to shaft 10. “The sleeve is of a rigid or semi-rigid material” and “is secured to shaft 10 at locations proximal and distal to the valve.” Column 5, lines 1-3. Moreover, “the sleeve is perforated or otherwise porous to allow for fluid communication between the interior of balloon 20 and valve 40.” Column 5, lines 5-7. Neither this embodiment, nor any other disclosed by Hegde et al. anticipates claim 1. A coating that is applied to the surface of the segment in a fluid state and cured, such as that of claim 1, adheres to the surface of the segment along the length of the coating and cannot be secured only at proximal and distal locations. If the coating of claim 1

were applied to shaft 10 of Hegde et al., the coating would adhere both to shaft 10 and valve 40. Therefore, the sleeve 50 of Hegde et al. does not correspond to the coating of claim 1.

One particular embodiment of sleeve 50 merits further discussion. Hegde et al. disclose that “for metal sleeves, a radiopaque material can be coated onto the sleeve.” Column 5, lines 19-20. This embodiment is inapposite for at least two reasons. First, claim 1 recites “the radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material.” Hegde et al. do not disclose what the radiopaque material that can be coated onto the sleeve might be, and do not teach or suggest that the radiopaque coating comprises a radiopaque material disposed within a non-metallic coating material. Second, claim 1 recites that the “radiopaque coating disposed on a surface of a portion of the elongated shaft” and “an expandable member affixed to the distal portion of the elongated shaft.” In Hegde et al., the radiopaque coating is not disposed on shaft 10 that has an expandable member affixed to a distal portion thereof, but rather is disposed on sleeve 50. No expandable member is affixed to a distal portion of sleeve 50. Therefore, the radiopaque material of this embodiment does not correspond to the coating of claim 1.

As Hegde et al. do not disclose each and every element of claim 1, Applicants submit that claim 1 is in condition for allowance. As claims 2, 4-5, 7-8, 12-13, and 15 depend from claim 1 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 22 has been amended, changing “means for rendering a portion...identifiable under fluoroscopy” to “coating means for rendering a portion...identifiable under fluoroscopy, wherein the coating means is applied in a fluid state and cured.” As discussed above with regard to claim 1, Hegde et al. do not disclose such liquid coating means. Applicants therefore submit that this claim is allowable over Hegde et al.

Claim 23 has been amended to include “the radiopaque portion applied to the surface of the segment of the shaft in a fluid state and cured.” For the reasons given above with respect to claim 1, Applicants submit that this claim is allowable over Hegde et al.

Claims 1, 2, 4, 5, 7, 8, 12, 13, 15, 17, 18, 21 and 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by Voyles et al. (U.S. Patent No. 6,540,721). Applicants respectfully traverse the rejection.

Voyles et al. disclose a balloon catheter having an inner tubular member and an outer tubular member. The balloon catheter has a radiopaque marker 24 that is formed either “by doping a portion of the distal inner tubular member” or from “a separate discrete member which is preformed and subsequently secured to the distal section of the distal inner tubular member 20.” Column 3, lines 34-35 and 41-44. Nowhere do Voyles et al. disclose a “radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the surface of the segment...in a fluid state and cured”; as claimed in independent claims 1 and 17. A separate discrete member that is preformed and subsequently secured to the inner tubular member results in a catheter that is structurally different from one where a radiopaque coating is applied in a liquid state and cured. For example, the surface interface between a cured liquid coating and the surface of the inner shaft is structurally different from the surface interface between two discrete members secured together by adhesive bonding, solvent bonding, or heat fusing. Applicants therefore respectfully submit that claims 1 and 17 are allowable over Voyles et al. As claims 2, 4, 5, 7, 8, 12, 13, 15 and 18 depend from either claim 1 or claim 17 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 21 has been amended to recite “where the non-metallic coating material is applied to the surface of the segment of the shaft in a fluid state and cured” and claim 22 has been amended to recite “coating means..., wherein the coating means is applied in a fluid state and cured.” Therefore for similar reasons discussed above with respect to claims 1 and 17, Applicants submit that these claims are allowable over Voyles et al.

Claims 1-5, 7, 8, 12, 13, 15, 17, 18 and 20-23 were rejected under 35 U.S.C. § 102(e) as being anticipated by Nishide et al. (U.S. Pub. No. 2004/0267280A1). Applicants respectfully traverse the rejections.

Nishide et al. disclose a coaxial balloon catheter having radiopaque markers 4 disposed on the inner tube. Nishide et al. say little about the radiopaque markers, but do state: “The material may be of any type, i.e., metal or resin. Moreover, the method of affixing the radiopaque marker 4 is not particularly limited.” Paragraph 86. However, Nishide et al. do not teach or suggest that the markers may be created by a “radiopaque coating comprising a radiopaque material disposed within a non-metallic coating material that is applied to the

surface of the segment...in a fluid state and cured,” as recited in claims 1 and 17. As discussed above, creating a radiopaque marker by applying a fluid to a shaft results in a catheter that is structurally different from a catheter created by affixing a separate discrete radiopaque marker to a shaft. Applicants thus submit that claims 1 and 17 are allowable over Nishide et al. As claims 2-5, 7, 8, 12, 13, 15, 18 and 20 depend from either claim 1 or claim 17 and contain additional elements, Applicants submit that these claims are also in condition for allowance.

Claim 21 has been amended to recite “where the non-metallic coating material is applied to the surface of the segment of the shaft in a fluid state and cured,” claim 22 has been amended to recite “coating means..., wherein the coating means is applied in a fluid state and cured” and claim 23 has been amended to recite “the radiopaque portion applied to the surface of the segment of the shaft in a fluid state and cured.” Therefore for the reasons discussed above with respect to claim 1, Applicants submit that these claims are in condition for allowance.

Applicants note that the Examiner considers claim 24 a product-by-process claim. Applicants know of no limitation where product-by-process claims can only be used where the product cannot be described structurally. As claim 24 is directed to the species of figure 2, which has been elected, Applicants request that withdrawal of claim 24 by the Examiner be reconsidered.

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Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

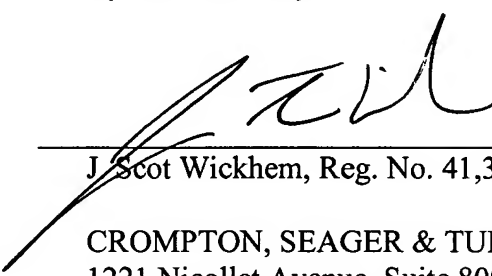
Respectfully submitted,

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By their Attorney,

Date: _____

July 13, 2005



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Attachments: 1 Replacement Drawing Sheet